



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,383	07/20/2001	Girish N. Nallur	13172.0007U1	2312
23859	7590	09/14/2005	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			CALAMITA, HEATHER	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/910,383

Applicant(s)

NALLUR ET AL.

Examiner

Heather G. Calamita, Ph.D.

Art Unit

1637

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 26 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☒ Note the attached Information Disclosure Statement(s). (PTO/5008 or PTO-1449) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

GARY BENZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

hgc

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments with respect to claims 1-29, 31-47, 56-58, 61, 68 and 71 are not persuasive. Applicants argue the claims require either the rolling circle replication primer comprises a capture tag or the cDNA comprises a capture tag and the capture tag is a hapten, ligand, ligand binding molecule, an antibody or an anti-antibody and that the 229 patent does not teach this. This is not persuasive because the 229 patent was not relied on for this teaching. The 024 patent was relied on for the teaching of a capture tag that is an antibody. The 024 patent teaches this in paragraph 0019 lines 19-22 as stated in the previous office action, specifically a nucleic acid tag coupled to a specific binding molecule, such as an antibody. Applicants' further argue the claims require the association between the rolling circle replication primers and the cDNA occurs via the capture tag and the 229 patent teaches an association of the primer and the target DNA molecule occurs via a nucleotide to nucleotide base pairing interaction between the sequences and not by interaction of a hapten or ligand. This is not persuasive because the nucleotide to nucleotide interaction meets the generic limitation of capture tag as a nucleotide can be a capture tag. Further the specific requirement in the claim defining the capture tag recites "capture tag is a hapten, ligand, ligand binding molecule, an antibody or an anti-antibody" the 229 patent was not relied on to meet this specific limitation rather the 024 patent which teaches a capture tag of an antibody was relied on. Applicants further argue no motivation for combining the references. This is not persuasive because it would be obvious to substitute an antibody for the nucleotide tag because it would improve specificity and enhance target discrimination. Additionally the 229 patent expressly teaches a hapten a ligand and a ligand binding molecule at col. 53 lines 54-56. Applicants further argue the combination of the 229 patent and the 024 patent would render the method of the 229 patent inoperable. This is not persuasive. The combination of the 024 patent with the 229 patent would simply change the operation of the methods disclosed in the 229 patent. One of skill in the art recognizes there exists a variety of ways to capture in a specific manner and the 024 patent provides motivation indicating that gap oligonucleotides enhance target dependency in LCR and this can be adapted for use in LM-RCA, and this method enhances target discrimination.

Applicants' arguments with respect to claims 37-41, 53-55, 62, 70 and 72 are not persuasive. Applicants argue the 229 patent fails to disclose or refer specifically to RT primers. This is not persuasive because patent 229 expressly states that RNA can be used with the methodologies disclosed. Therefore a practitioner of ordinary skill in the art recognizes the need for using RT primers when working with RNA. Additionally the 229 patent teaches cDNA which inherently requires the use of RT primers. Moreover primers are primers. RT primers (primers for producing cDNA) are not structurally different from DNA primers (primers for producing DNA), therefore because the combination of the 229 patent and 024 patent renders the instant invention obvious with respect to DNA primers then it necessarily renders the instant invention obvious with respect to RT primers.

Applicants' additional arguments for claims 39-41 are not persuasive. Applicants argue the 229 patent fails to teach the cDNA strands comprise a capture tag and the capture tag is selected from the group consisting of biotin, digoxigenin, bromodeoxyuridine or other haptens. Applicants argue while the 229 patent discloses the capture tags, the tags are not disclosed on cDNA. This is not persuasive because the 229 patent discloses RNA and further discloses cDNA (see example 4).

Applicants' additional arguments for claims 46 and 47 are not persuasive for the same reasons outlined above.

Applicants' arguments with respect to claim 30 are not persuasive. Applicants reiterate previously stated arguments relating to the deficiencies of the combination of the 229 and 024 patents and additionally state that Waggoner et al. fail to supplement the elements missing from the 229 and 024 patents. This is not persuasive for the reasons outlined above.

Applicants' arguments with respect to claims 48-52, 69 and 73 are not persuasive. Applicants reiterate previously stated arguments relating to the deficiencies of the combination of the 229 and 024 patents and additionally state that Cao et al. fail to supplement the elements missing from the 229 and 024 patents. This is not persuasive for the reasons outlined above.

Applicants' arguments with respect to claim 59 and 60 are not persuasive. Applicants reiterate previously stated arguments relating to the deficiencies of the combination of the 229, 024 and patents and additionally state that Shoemaker et al. fail to supplement the elements missing from the 229 and 024 patents. This is not persuasive for the reasons outlined above.